Exhibit 5

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LETTER

Letter to FDA Commissioner Jane Henney on the Restrictions on Mifepristone

Document Date: September 22, 2000

Jane Henney, M.D.
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Henney:

We understand that the Food and Drug Administration ("FDA") is considering a variety of restrictions on the distribution and administration of the drug mifepristone. As an organization committed to women's health and reproductive freedom, we write to urge you to consider the serious health consequences of any restrictions that would curtail access to this drug.

A primary promise of mifepristone is its ability to provide access to earlier abortion options for women who live far from a surgical abortion provider. Restrictions on the drug – particularly any limitation on who can administer it – would rob women of mifepristone's promise of access to earlier, and therefore in many cases safer, abortions. Moreover, such restrictions are not necessary, where the FDA has already found mifepristone to be safe and efficacious.1 Considered in the broader context of the provision of reproductive health care in this country, restrictions that limit who can provide the drug and that thereby reduce access will disserve, not further, women's health. Because the FDA's mandate is to further public health, it should approve mifepristone without the considered restrictions.

Restrictions on mifepristone that unjustifiably limit the number of licensed providers will serve to delay abortions to the detriment of women's health. Mifepristone is available for procedures used between the earliest point at which a pregnancy can be confirmed and 49 days (or 7 weeks) of pregnancy, whereas many facilities do not perform surgical abortions until 6 to 8 weeks. In addition, many women experience further delay in their attempts to obtain a surgical abortion. A primary cause of this delay is lack of access to an abortion provider.

The problem of access is pervasive. In 86% of counties in the country, there is no abortion provider.2 South Dakota, for example, has only one abortion provider, leaving women to travel hundreds of miles for care.3 Women who live far from a provider often have difficulty arranging the procedure: They face difficulties scheduling an absence from home or work for the

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Any delay in obtaining an abortion is significant because gestational age is an important determinant of medical risk. While surgical abortions are extremely safe, the risk of death from abortion increases approximately 30 percent with each week of gestation from 8 weeks of pregnancy measured from the woman's last menstrual period (lmp) to 20 weeks lmp.5 The risk of major medical complications increases approximately 20 percent with each week of gestation from 7 weeks onward.6

Thus, for example, without mifepristone, a woman located several hundred miles away from the nearest surgical abortion provider might be unable to obtain an abortion until the 10th week of pregnancy. If mifepristone were available in her community, she could obtain an earlier non-surgical abortion that would possibly be safer.

Mifepristone can serve women's health by increasing the number of abortion providers and making the procedure available outside the traditional surgical abortion setting. In a recent survey, 31% of gynecologists who have never performed surgical abortions or have not performed them in the past five years stated that they were "very likely" or "somewhat likely" to prescribe mifepristone if it were available.7 The promise is even greater when other physicians are considered. Thirty-one percent of family practice physicians, 98% of whom do not perform surgical abortions, similarly indicated that they were "very" or "somewhat" likely to prescribe mifepristone.8

Moreover, some women may prefer a non-surgical abortion and may be motivated to seek care earlier if such an option were available. The fact that mifepristone is available only in the first few weeks of pregnancy is part of the publicity surrounding the drug. In contrast, many women are unaware of the fact that surgical abortions are safer if performed earlier in pregnancy. Thus, wide access to mifepristone may steer women away from later, and potentially riskier surgical abortion procedures.

In approving mifepristone, the FDA should not focus narrowly on what may, in a perfect world, be the ideal conditions for a single administration of the drug. Rather, as an agency dedicated to protecting public health, the FDA should also consider the health advantages of increased access to earlier and safer abortion options. Any restrictions by the FDA limiting those who may prescribe mifepristone would dramatically decrease its availability and would thus rob women of one of the drug's major health benefits. We urge you to consider the broad health implications of any such restrictions.

Sincerely,

Laura Murphy
Director, Washington National Office

Catherine Weiss
Director, Reproductive Freedom Project

Endnotes:

1). See Letter from FDA to Population Council (Sept. 18, 1996).

2). Stanley K. Henshaw, Abortion Incidence and Services in the United States, 1995-1996, 30 Fam. Plan. Persp. 263, 266

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effort to impose such a requirement, or to otherwise limit the physicians who can provide abortions, is dubious at best. See Pro-Choice Mississippi v. Thompson, No. 3:96CV596BN, slip op. at 18 (S.D. Miss. Sept. 28, 1996) (preliminarily enjoining regulations requiring physicians providing abortions to have completed an American Medical Association-approved residency in obstetrical/gynecology). The United States Supreme Court has held that a physician licensed by the state possesses sufficient qualifications to perform an abortion. See Doe v. Bolton, 410 U.S. 179, 199-200 (1973); Word v. Poelker, 495 F.2d 1349, 1352 (8th Cir. 1974) ("We are referred to no other single surgical procedure where doctors are required to 'prove up' their overall fitness as they are here."); Mahoning Women's Ctr. v. Hunter, 610 F.2d 456, 460 (6th Cir. 1979) (holding that the city may not define the term "physician" to mean more than "a physician currently licensed by the State") (quoting Roe v. Wade, 410 U.S. 113, 165 (1973))), vacated and remanded on other grounds, 447 U.S. 918 (1980).

4). See Ada Torres & Jaqueline Darroch Forrest, *Why Do Women Have Abortions, 20 Fam. Plan. Persp. 169, 174 (1988).*

5). See Herschel W. Lawson et al., *Abortion Mortality, United States, 1972 through 1987, 171 Am. J. Obstet. & Gynecol. 1365, 1367 (Table II) (1994).*

6). Christopher Tietze & Stanley K. Henshaw, *Induced Abortion: A World Review 1986, at 103 (The Alan Guttmacher Institute, 6th ed. 1986).*

7). The Henry J. Kaiser Family Foundation, *A National Survey, Views of Women's Health Care Providers on Abortion: An Update on Mifepristone 2 (2000) <.*

8). *Id. at 2-3.*

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